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COMMENTS OF THE TOBACCO INSTITUTE ON THE
PROPOSED REGULATION OF CIGARETTE
FILTERS AS MEDICAL DEVICES
(Docket No. 77D-0367)

On September 27, 1977, the Anesthesiology Device Classification Panel (an FDA advisory committee) recommended that "filters, tobacco smoke, attached" and "filters, tobacco smoke, unattached" be classified as Class III devices under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. In the Federal Register of November 29, 1977 (42 Fed. Reg. 60792), FDA announced that the Panel's recommendations were available for public review and invited the submission of information, data, and views on them.

These comments are submitted by The Tobacco Institute, Inc., a nonprofit association representing major manufacturers of cigarettes, with respect to the Panel's recommendation on attached filters.*/ The recommendation that cigarette filters be regarded as medical devices is legally erroneous and should not be adopted by FDA.

Introduction

The Panel came to consider the status of cigarette filters in an unusual way. Cigarette filters were not on

*/ These comments do not deal with the recommendation on unattached filters. Unattached filters are a product wholly different from filter cigarettes, sold by a different group of manufacturers, and with different labeling.

the list of medical devices drawn up by FDA and presented to the various classification panels for consideration. Instead, the issue of whether cigarette filters are devices was first raised by Aaron Levine, a Washington lawyer and the consumer representative on the Pulmonary Device subcommittee of the Anesthesiology Panel. In the last session before the final report of the committee was due, Mr. Levine made a presentation to the Panel, which then adopted his recommendation that cigarette filters be classified as Class III medical devices.

It is not surprising that FDA did not list cigarette filters as medical devices, since they are not and cannot be so regarded under the provisions of the Federal Food, Drug, and Cosmetic Act. Decades after filter cigarettes appeared on the market, and 40 years after the Act was passed by Congress, the claim that cigarette filters are medical devices has first been raised. This sudden interest in cigarette filters is not due to some new change that now subjects them to FDA jurisdiction. Instead, the notion that cigarette filters are medical devices is simply a variation on recent efforts to persuade a federal agency to assert unauthorized jurisdiction over cigarettes.

There have been a number of such attempts to distort regulatory statutes intended for other purposes in an effort to reach cigarettes. Several years ago antismoking partisans tried to have the Consumer Product Safety Commission take jurisdiction over cigarettes on the ground that they were a

"hazardous substance." This attempt was quashed by Congress. More recently, FDA was asked (but properly declined) to take jurisdiction over cigarettes on the theory that they were drugs -- the same theory that the Federal Trade Commission had put forward 25 years earlier until it was rejected by the courts. Now, once again FDA is urged to take jurisdiction over cigarettes, this time on the theory that filter cigarettes (comprising the vast majority of all cigarettes) are in reality medical devices -- a conclusion heretofore never argued despite the intensity of the smoking and health controversy and the long history of FDA regulation of medical devices.

As these comments will show, cigarette filters are not "devices" under the Federal Food, Drug, and Cosmetic Act. A product may be classified as a device only if its manufacturer represents it as useful in preventing or mitigating a disease, and such representations are not made for filter cigarettes. No health claims are made for filter cigarettes, and under the law, no determination that cigarette filters are devices can be based either on conjecture about purchasers' motivations or on manufacturers' disclosures concerning smoke components.

It will also be shown in these comments that any assertion by FDA of jurisdiction over cigarette filters would be unlawful because such regulation would conflict with

federal legislation dealing specifically with cigarettes. This legislation precludes use of the essential mechanisms by which FDA regulates medical devices and, more generally, makes clear the congressional intent that administrative agencies such as FDA are not to regulate cigarettes.

I. Cigarette Filters Are Not Devices

Under clearly established law a product may be regulated as a medical device under the Federal Food, Drug, and Cosmetic Act ("the Act") only if the seller makes health claims for the product. No such claims are made for filter cigarettes, nor can any such claims be inferred from cigarette advertising or from speculation about consumers' intentions. Accordingly, filter cigarettes are not subject to regulation as medical devices.

A. The Seller's Representations Determine Whether Cigarette Filters Are Devices.

Section 201(h) of the Act defines the term "device" to mean

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is --
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> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
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> (3) intended to affect the structure or any function of the body of man or other animals, and
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> which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

In support of their position that cigarette filters should be regulated as devices, Mr. Levine and Dr. Ream, the Panel chairman, both contended that filters are "intended for use in the . . . mitigation . . . or prevention of disease." (Tr. 114, 129.) No other statutory clause was cited at the meeting, and none is even arguably applicable.

Court decisions make clear that the "intended" uses of an article are determined by reference to the representations and claims that are made in its labeling, advertising, or other promotion. See, e.g., National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (2d Cir. 1974), cert. denied, 420 U.S. 946 (1975); United States v. An Article . . . "Sudden Change," 409 F.2d 734, 739 (2d Cir. 1969); United States v. Article of Drug . . . B-Complex Cholinos Capsules, 362 F.2d 923 (3d Cir. 1966); Nature Food Centres, Inc. v. United States, 310 F.2d 67 (1st Cir. 1962), cert. denied, 371 U.S. 968 (1963);

United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953).

This legal principle was most recently stated in National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325 (2d Cir. 1977), in which the court of appeals upheld a decision invalidating an FDA regulation that had declared high-potency formulations of vitamins A and D to be "drugs" within the meaning of the Act without regard to their sellers' claims. FDA's theory was that these formulations were drugs because many persons in fact used them for therapeutic purposes. In rejecting this theory, the court said: "The vendors' intent in selling the product to the public is the key element in this statutory definition." */ 557 F.2d at 333.

The teaching of these decisions is that a particular use may be considered to be a product's intended use only if the seller has affirmatively made representations that the product is suitable for such use. The courts' concern in these cases was not with the actual effects of the product or with the purchasers' intentions, but only with the sellers' claims.

This approach is consistent with and, indeed, is required by the Act's legislative history. Congress intended

*/ So far as is relevant here, the definition of "drug" under the Act is identical to the "device" definition. Both definitions require that the article be "intended for use in the . . . mitigation . . . or prevention of disease." See § 201(g)(1) and (h)(2) of the Act.

to place the manufacturer in control of his product's regulatory status; only the manufacturer's claims were to be considered in ascertaining whether FDA had jurisdiction over the product:

> The manufacturer of the article through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product.

S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935).

In denying a petition to have cigarettes regulated as drugs, FDA recently acknowledged that the seller's representations are dispositive. Commissioner Kennedy stated:

> The petitioners have presented no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are "intended to affect the structure or any function of the body of man . . ." 21 U.S.C. § 321(g)(1)(C). Statements by the petitioners and citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies are not evidence of such intent by the manufacturers or vendors of cigarettes, as required under the provisions of 21 U.S.C. § 321(g)(1)(C).*/

*/ Letter from Donald Kennedy, Commissioner of Food and Drugs, to Mr. John F. Banzhaf, dated December 5, 1977.

This letter properly applies the clear principle established by the courts and the legislative history of the Act: The seller's representations are the basis for determining the intended use of a product.

B. The Anesthesiology Panel's Recommendation Is Based On An Erroneous Legal Standard Since Filter Cigarette Manufacturers Do Not Make Health Claims.

Health claims are not made for cigarette filters. Any review of cigarette labeling and advertising plainly reveals that filter cigarettes are being sold only for their taste, smoking enjoyment, and related characteristics. Manufacturers do not represent that cigarettes prevent or mitigate diseases. Since, as has been shown, a manufacturer's representations determine his product's status, the Panel should have concluded that filter cigarettes are not devices.

At least one of the Panel members based his determination that cigarette filters are devices on matters unrelated to the seller's claims. Dr. Downes stated his view that the manufacturer's claims were irrelevant:

> And therefore whether the industry claims it or not[,] the fact is they are interpreted by a significant percentage of the general public as devices that mitigate against disease. So I see no problem in my mind in classifying it as a medical device.

(Tr. 141).

The Panel reviewed no labeling or advertising for filter cigarettes that it found made overt health claims. In his statement to the Panel, Mr. Levine presented a handful of advertisements which he construed as making health claims, although he admitted that the claims he perceived in these advertisements were not obvious:

> I am not able to present to you the strong, hard health claims that I was able to present in the humidifiers. We are going to get into a much more subtle area.

(Tr. 116.)

Drs. Ream and Hopewell agreed that the advertisements presented by Mr. Levine contained no clear health claim but relied instead on what they perceived to be "innuendo" in the advertisements in deciding that cigarette filters were medical devices. (Tr. 133-34.)

In summary, the Panel's recommendation appears to have been predicated on a misconception of the applicable law, and one of the committee members explicitly based his decision on a legally erroneous standard. The only health claims perceived were acknowledged, even in the view of the Panel, to be "innuendo." Since FDA has the burden of proof when attempting to establish the existence of facts necessary to give it jurisdiction over a product, the Panel's reliance

on alleged insinuations in advertisements is clearly an inadequate basis for regulatory action.

At any rate, even if the few advertisements examined by the Panel were determined to be making health claims, that determination would apply only to the advertised cigarettes and not to other brands.*/ The claims made by one vendor regarding a particular product may not be attributed to other vendors or to similar products. For example, it has been firmly established that drug claims made for one brand of cigarettes do not result in other brands of cigarettes being regarded as drugs. Compare Federal Trade Comm'n v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 575 (S.D.N.Y. 1952), aff'd 203 F.2d 955 (2d Cir. 1953), with United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959). By the same token, the advertisements examined by the Panel cannot support the notion that filter cigarettes as a class are subject to regulation as devices.

In short, there is no evidence whatever that filter cigarette manufacturers make representations that their products prevent or mitigate disease. Accordingly, filter cigarettes may not lawfully be classified as devices under the Act.

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*/ Dr. Dorsch's comments indicate that she recognized this result. See Tr. 159.

C. No Health Claim Can Be Inferred.

Although we think this aspect of the decision is unjustified, one court has recognized an exception to the general rule that intended use is determined solely by a vendor's representations. In National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 788-89 (2d Cir. 1974), the court held in effect that a substance could be presumed to be intended for drug use if it was in practice used "almost exclusively" for therapeutic purposes. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 336 (2d Cir. 1977); National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 703 (2d Cir. 1975).

The court nevertheless invalidated FDA's attempt to classify as drugs all products containing more than specified amounts of vitamins and minerals, noting that "a significant number of persons have indisputable nutritional need for potencies exceeding the upper limits . . . ." 540 F.2d at 789. Therefore no assumption could be made that the products were being used almost exclusively for therapeutic purposes. As the court stated, "[T]he vendor of such a product can in good faith intend it for nontherapeutic use." Id.

Even if the exception apparently recognized (but not applied) in this case were correct, cigarette filters could not be presumed to be intended for a medical purpose. Filter cigarettes are sold and purchased for reasons having no relation to the mitigation or prevention of disease.

A primary motivation for the purchase of filter cigarettes is taste -- filter cigarettes are milder in taste than unfiltered cigarettes. The preference for filter cigarettes that has developed in recent years parallels the change in taste in other products. For example, the trend in sales of alcoholic beverages has been away from stronger tasting liquors, such as scotch and bourbon, toward lighter tasting (or tasteless) drinks, such as vodka and wines. Over the years, taste in coffee has similarly changed from stronger to lighter types. And tracking these trends in flavor preference have been analogous changes in other product lines -- such as increased desire for simplicity in design and the "natural look" in cosmetics. It is not surprising that these consumer tastes should be reflected in increased sales of milder tasting filter cigarettes and reduced consumption of stronger tasting unfiltered brands.

The esthetic advantage of filter cigarettes is undoubtedly also a factor to many consumers and has been since their introduction. A filter prevents tobacco particles from entering the smoker's mouth, which is a consideration many smokers find desirable.

Finally, the influence of fashion cannot be discounted. Some cigarette brands are more fashionable than others, and the filter plays a part in their appeal.

In short, even under the criterion announced in National Nutritional Foods, filter cigarettes are not devices. There has been no showing, nor could there be any showing, that filter cigarettes are used "almost exclusively" for safety or health reasons.

D. Low "Tar" And Similar Claims Are Not Device Claims Under The Law.

The Panel did not identify the health claim that it perceived in filter cigarette advertising. Since much current advertising focuses on the levels of "tar" and other ingredients in cigarette smoke, however, it is worthwhile pointing out that such advertising clearly does not constitute health claims. That conclusion remains true even when considered against the background of theories alleging relationships of cigarette smoking to disease. A representation regarding the reduction of a smoke component does not constitute a device claim. Moreover, such a representation would not be a device claim even if it were to be accompanied by an express statement relating the reduction to health effects.

Understanding the true nature of a low "tar" or similar claim begins with an accurate definition of the product. The Panel was able to recommend that filter cigarettes be regulated as medical devices only by considering the filter as a product separate from the rest of the cigarette. In fact, however, cigarette manufacturers do not sell cigarette filters

separately to the public. A cigarette, whether filtered or unfiltered, is an article designed to produce tobacco smoke, and the complete cigarette, not its separate components, is the product being marketed. Those manufacturers who emphasize the effectiveness of the filter or the "tar" content do so as a means of describing the tobacco smoke. The filter is merely one means to achieve this end, and not the product itself.

If tobacco is modified so as to produce low "tar" smoke without use of a filter, there would clearly be no argument that the cigarette was a medical device -- the Panel's recommendation was based on the presence of an attached filter. A difference in regulatory status based on whether or not a filter is used to achieve the "tar" reduction is plainly specious, however, because it is unrelated to the product actually being marketed -- an article for producing tobacco smoke.

Once it is recognized that filter cigarette manufacturers are selling cigarettes -- not filters -- it becomes obvious that representations related to the reduction of smoke components are not device claims. This conclusion follows from the legal distinction between claims about the presence in a product of an allegedly beneficial ingredient and claims about the absence or reduction of an allegedly deleterious ingredient. While FDA and the Federal Food, Drug, and Cosmetic Act recognize the possibility of drug or device claims arising

out of the former, they do not recognize that possibility with respect to the latter. Removing an ingredient claimed by some to be harmful from a product and announcing its removal does not convert the product into a drug of device.

In the only judicial ruling on point, the court in Federal Trade Comm'n v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 575 (S.D.N.Y. 1952), aff'd 203 F.2d 955 (2d Cir. 1953), squarely held that representations about a product's lack of adverse effects are not therapeutic claims. That action was brought by the FTC under the Federal Trade Commission Act, which in 15 U.S.C. § 55 incorporates the same definitions of "drug" and "device" as in the Federal Food, Drug, and Cosmetic Act. The court rejected the FTC's contention that certain cigarettes were drugs because they were represented as preventing irritation and having no adverse effect on smokers. 108 F. Supp. at 573, 575. Distinguishing earlier cases in which cigarettes claiming beneficial effects were held to be drugs, the court held that a representation of a "non-adverse" effect did not make a cigarette a drug. 108 F. Supp. at 575.

Although FDA appears not to have expressly articulated this principle, its validity is evident from the agency's treatment of analogous claims. If a low "tar" representation for a cigarette is a health claim, then many widely made claims for foods would also be medical claims and would render the

products drugs. For example, various diseases have been linked to sugar, cholesterol, sodium, and obesity, but foods promoted as low in cholesterol, sodium, fat, calories, or sugar are not regarded as drugs by FDA.*/ As another example, "contains no preservatives or other additives" is not regarded as a drug claim despite the implication that additives and preservatives are bad for one's health. If filter cigarettes are devices because of low "tar" claims, then all these products would be drugs.

A manufacturer may not only claim reduction or elimination of a deleterious ingredient without rendering the product a drug or device, he may also explicitly identify the hazard associated with the deleted ingredient.

Thus, for example, a food product could be labeled "Contains no saccharin -- which has been found to cause cancer in laboratory animals and may be hazardous to your health," and the product would not thereby become a drug. Without becoming a drug, a product could claim to be free of fluorocarbon propellants and note that such products may harm the ozone layer and accordingly human health. Labeling of a sugar-free chewing gum may, without making the product a drug,

*/ One must recognize the distinction between, on the one hand, unproven and hence potentially misleading claims and, on the other hand, drug or device claims. FDA limits the nature of a low-cholesterol claim to a specific format (21 C.F.R. § 101.25) because of the unestablished connection between cholesterol and disease, but there is no suggestion that a low cholesterol claim makes the food into a drug.

refer to the link between sugar and dental caries and assert that the product "does not promote tooth decay." A reduced calorie food product could describe the medical dangers associated with obesity without becoming a drug.

FDA regulations have recognized the examples of hypoallergenic foods and cosmetics (21 C.F.R. §§ 105.62, 701.130).*/ Under these regulations a food or cosmetic may explicitly represent that it is less likely to cause an allergic reaction because certain ingredients are not present. Such a representation does not, however, make the product a drug.

Applying these principles to cigarettes, it is indisputable that low "tar" and other claims related to reduction of smoke components are not representations that would make cigarettes devices. Since, as shown above, explicit statements can be made about the consequences of eliminating ingredients without rendering them drugs or devices, it is clear a fortiori that a cigarette is not a drug or device based on the subtle implications in advertisements apparently discerned by the Panel members.

E. The Consequences of Regulating Filter Cigarettes As Devices Demonstrate That The Device Law Was Not Intended to Apply to Them.

If cigarette filters are declared to be devices on the theory that they are being offered for the prevention or mitigation of disease, the Act requires a demonstration

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*/ The regulation on hypoallergenic cosmetics was recently invalidated by a court for reasons unrelated to the point. See 43 Fed. Reg. 10559 (Mar. 14, 1978).

that the filters are effective for their intended use. It has not been shown, however, that "tar," or any component as found in tobacco smoke, causes disease, nor have any hazards been established for various levels of such substances.

As a result, filter cigarette manufacturers would be unable to meet the burden of proof imposed on device manufacturers, and FDA would evidently be obliged to ban filter cigarettes. The public interest would plainly not be served by such action. Smokers would be denied the milder taste and other advantages of filter cigarettes, and the outcry from consumers would undoubtedly be substantial. All would rightly wonder how the public interest was being served by an FDA ban on filter cigarettes (and only filter cigarettes). Interpreting a regulatory statute so as to result in a ban that would be universally perceived as misguided and irresponsible further demonstrates that, as matters of good logic, common sense, practical dictates of the market place, and public policy, cigarette filters were not meant to be regulated as medical devices.

Even if a ban were avoided, regulating filter cigarettes as devices could unnecessarily stultify the development of new types of filters by subjecting them to lengthy and costly clearance procedures involving difficult or insurmountable burdens of proof. Such obstacles would be raised by legislation designed to further the public health although, in the context

of filter cigarettes, compliance with the Act's requirement cannot possibly benefit the public health. This paradox illuminates the irrationality in attempting to regulate filter cigarettes as devices. Filter cigarettes do not satisfy the definition of a device and, even if they did, it would be senseless to regulate them as devices.

II. FDA Regulation of Cigarette Filters Would Conflict With Federal Legislation Dealing Specifically With Cigarettes

In legislation enacted in 1965 and 1969, Congress established a comprehensive program to deal with smoking and health issues and reserved for itself the exclusive authority to formulate policies concerning the labeling, advertising, and sale of cigarettes.*/ Assumption of regulatory authority over cigarette filters by FDA would necessarily bring the agency into conflict with the preemptive purpose of these Acts.

A. Congress Has Preempted the Field of Smoking and Health Regulation.

The express provisions and legislative history of the Cigarette Acts of 1965 and 1969 make clear Congress' intent to preclude FDA and other federal administrative agencies from requiring health-related labeling different from that

*/ 15 U.S.C. §§ 1331-1340.

required by the Acts. In addition, those Acts make clear the congressional intent to preclude any agency from prohibiting or restricting the sale of cigarettes.

When it adopted the two Cigarette Acts, Congress sought to balance the complex interests involved in the smoking and health controversy. That balance was reflected in the statute itself, which stated that its purpose was:

> [T]o establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby --
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> (1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and
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> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health. */

Congress decided in 1965 that the continued sale and advertisement of cigarettes should be permitted, but directed manufacturers to provide a prescribed warning to the smoking public concerning the asserted health hazards of

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*/ 15 U.S.C. § 1331.

smoking. The Cigarette Labeling and Advertising Act of 1965 spelled out the health-related statement to be required on all cigarette packages, and the Act prohibited all other health-related labeling:

> No statement relating to smoking and health, other than the statement required by Section 1333 of this title, shall be required on any cigarette package. */

Congressional preemption of the field of smoking and health was not limited to questions of labeling and advertising. Congress retained for itself the sole authority to make regulatory policy in the area, including the power to decide whether the sale of cigarettes should be restricted.

This preemptive intent has been clearly recognized by FDA in the past. In 1972 congressional hearings, for example, FDA Commissioner Charles C. Edwards stated:

> Congress has clearly enunciated its policy on cigarettes in section 2 of the Public Health Cigarette Smoking Act. This provides that the public should be adequately informed about the hazards of smoking and that commerce and the national economy should be protected to the maximum extent consistent with this declared policy . . . .
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> This Act also we believe demonstrates that the regulation of cigarettes is to be the domain of Congress. No statement relating to smoking and health can be required on cigarettes except the warning prescribed by Congress.

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*/ 15 U.S.C. § 1334(a).

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> In sum, labeling or banning cigarettes is a step that can be taken only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent. */

Commissioner Edwards' statement rested on a solid foundation. The 1965 and 1969 Acts reflect the intent of Congress as to how cigarettes are to be marketed. A stated purpose of the Acts is "to establish a comprehensive Federal program to deal with cigarette labeling with respect to any relationship between smoking and health." **/ In addition, the Acts demonstrate a determination that cigarettes shall be marketed, and that Congress alone will decide what restrictions, if any, will be placed on their sale. The cigarette acts direct HEW and FTC to submit annual reports on smoking questions with "recommendations for legislation." ***/ But, as the House Interstate and Foreign Commerce Committee stated in its report on the 1965 Act:

> The determination of appropriate remedial action in this area . . . is a responsibility which should be exercised by the Congress after considering all facets of the problem.****/

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*/ Hearings on the Public Health Cigarette Amendments of 1971 Before the Consumer Subcommittee of the Senate Commerce Committee, 92d Cong., 2d Sess. 242 (1972).

**/ 15 U.S.C. § 1331.

***/ 15 U.S.C. §§ 1337(a), (b).

****/ H.R. Rep. No. 449, 89th Cong., 1st Sess. 3 (1965).

B. Regulation of Cigarette Filters As Medical Devices Would Necessarily Conflict With the Cigarette Acts.

There are basically only two kinds of action open to FDA if it determines that cigarette filters are devices. It can prohibit some or all filters, or it can require certain labeling concerning the filters.*/ Neither type of action would, however, be permissible under the 1965 and 1969 Cigarette Acts.

1. The Standard Setting Authority for Devices Could Not Be Enforced.

The essential feature of device regulation under the Federal Food, Drug, and Cosmetic Act is the statutory prohibition on the sale of devices that FDA determines have not been proved safe and effective. Thus, if FDA were to regulate cigarette filters as devices, the agency would prohibit those filters that did not meet its established criteria.**/

In the case of filter cigarettes, however, it is impossible to ban a filter without also banning the cigarette. A filter cigarette is developed as a unit. Substitution of the filter with a different kind would change the taste and

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*/ FDA also has authority over minor aspects of production and marketing such as sanitation, but these controls are collateral to the basic purposes of device regulation.

**/ The criteria would vary in form depending on whether FDA regulated cigarette filters through premarketing approval, performance standards, or general postmarketing controls, but the result in any case would be the same.

other characteristics of the cigarette, and the resulting cigarette would not be the same as the one previously marketed.

Any FDA required change in the composition of a filter cigarette would plainly be inconsistent with the Cigarette Acts, which determined that cigarettes should continue to be marketed. An FDA imposed reformulation of filter cigarettes would certainly damage the sales of the brands affected and could seriously disrupt all cigarette marketing, since approximately 90 percent of the cigarettes sold in the country have filters attached. FDA action that reduced sales of some or all cigarette brands would amount to a restriction of the kind prohibited by Congress.

The congressional intention that administrative agencies not tamper with cigarettes in a way that might affect their marketing has been repeatedly evidenced. Discussing proposals by the FCC to ban cigarette advertising in broadcast media and the FTC to require health warnings in print advertising for cigarettes, the House Interstate and Foreign Commerce Committee said in its report on the 1969 Act:

> It is obvious that if [the proposed] regulations are allowed to go into effect . . . they would have an impact on areas far beyond those intended by Congress to be regulated by these agencies. The regulations. . . . would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities.

> These activities cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.
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> * * *
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> Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy (see section 5(b) of the Act), has stated its intention to be the exclusive policymaker on the subject matter, at least until July 1, 1969 (see section 10 of the Act), and has given strong indication of its intention to continue to do so.
>
> Therefore, the Committee feels it is incumbent on the Congress to act on the reported legislation in order to prevent intrusion by the Federal Communications Commission and the Federal Trade Commission into basic areas of policymaking which it has reserved to itself.*/

Congress enacted the proposed legislation as the Public Health Cigarette Smoking Act of 1969.

In its unpublished opinion in American Public Health Association v. Consumer Product Safety Comm'n, C.A. No. 74-1222 (D.D.C. April 23, 1975), the district court disregarded these clear congressional directives and determined that the Consumer Product Safety Commission could lawfully exercise jurisdiction over cigarettes under the Federal Hazardous

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*/ H.R. Rep. No. 91-289, 91st Cong., 1st Sess. at 4-5 (1969) (emphasis added).

Substances Act to impose cautionary label statements different from those specified by Congress or to ban entirely the sale of high-tar cigarettes. */

Congressional response to the APHA decision was rapid and explicit. On June 24, 1975, the Senate Commerce Committee and the House Committee on Interstate and Foreign Commerce reported bills that eliminated CPSC's authority to regulate cigarette labeling or to ban cigarettes under the FHSA. **/ The bill reported to the House simply eliminated tobacco and tobacco products from the coverage of the FHSA. The Senate committee's bill permitted CPSC to retain jurisdiction over tobacco products as an "ignition source." Five of the Senate committee members objected to this limited grant of authority, stating that:

> The Consumer Product Safety Commission lacks the expertise and the resources to deal with this question. It does not have the competence to make critical judgments as to the relationship between burning rates of tobacco products and necessarily intertwined and paramountly important questions relating to the components of cigarette smoke. These are all aspects of the basic regulation of tobacco products, particularly cigarettes, which Congress has retained for final decision.

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*/ The district court's decision was never tested on appeal, but was vacated as moot when Congress repudiated its holding. The decision, which contravenes the plain language of the preemptive provisions of the cigarette acts and the clear legislative intent to reserve the field of smoking and health for congressional policymaking, is not entitled to serious consideration. It should not govern the determination whether cigarette filters may be regulated under the Federal Food, Drug, and Cosmetic Act.

**/ S. Rep. No. 94-251, 94th Cong., 1st Sess. (1975); H.R. Rep. No. 94-325 (1975).

> based on input from all agencies of the government. The Congress, being the only body in a position to evaluate all pertinent factors, should continue its fully-considered policy of retaining final authority on this area.*/

In the end, this position prevailed. The Conference Committee deleted the provisions granting the Commission authority over cigarettes as an ignition source,**/ and Congress enacted a statute that eliminated all CPSC authority to regulate cigarettes.

Just as Congress saw the issue of cigarettes as ignition sources inextricably tied to cigarette policy as a whole, so also would it view the regulation of cigarette filters as intertwined with national policy on tobacco products. An FDA ban on certain filters would bring the agency squarely into conflict with the preemptive purpose of the Cigarette Acts.

2. FDA Could Not Require Filter Cigarettes To Be Labeled As Devices.

The Cigarette Acts not only preempt FDA's authority to approve and disapprove specific filters, they also preempt FDA's authority to require the labeling that would be necessary if filters were regulated as devices.

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*/ S. Rep. No. 94-251, 94th Cong., 1st Sess. 45 (1975) (emphasis added).

**/ H.R. Rep. No. 94-1022, 94th Cong., 2d Sess. 16 (1976).

Under Section 502(f) of the Act, a device must bear "adequate directions for use." FDA regulations define "adequate directions for use" for a device as including "statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes or uses for which it is prescribed, recommended, or suggested . . . ." 21 C.F.R. § 801.5(a). It is clear from this regulation -- and from the law generally -- that filter cigarette labeling would have to include a statement of the filter's indicated use if the filter is a device.*/ But any such statement would necessarily constitute a statement about smoking and health, which is expressly prohibited by the 1965 and 1969 Cigarette Acts.**/

The regulatory scheme for medical devices is wholly inappropriate for products for which FDA cannot regulate the labeling claims. The scheme depends entirely on FDA's determining the accuracy of claimed benefits and limiting label claims to those benefits -- an impossibility where FDA cannot regulate the labeling. Moreover, the labeling information is not limited

*/ Mr. Levine apparently had this requirement in mind when he told the Panel, "These devices and device manufacturers will have to come before the FDA with labeling, will have to come before the FDA with testing, will have to come before the FDA with their warnings and their advertising." (Tr. 118.)

**/ "No statement relating to smoking and health, other than the statement required by Section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334(a).

to a general statement of a device's indicated use. Very specific language may be necessary to distinguish among similar devices of varying effectiveness. If, for example, the X device prevents seven different diseases while the similar Y device mitigates only one, that difference must be communicated in labeling if the regulatory scheme is to be meaningful. But in the case of cigarettes absolutely no health related labeling could be required, and the statutory plan for regulating medical devices cannot therefore be implemented.

In summary, the Cigarette Acts would prevent FDA both from banning types of filter cigarettes and from requiring labeling related to health benefits. With these essential elements of medical device regulation preempted, it is obvious that Congress did not intend for cigarette filters to be regulated as devices.

CONCLUSION

We have shown in these comments that cigarette filters are not "devices" within the meaning of the Federal Food, Drug, and Cosmetic Act. A product can be regulated as a medical device only on the basis of the manufacturer's health claims, and filter cigarette manufacturers simply do not make such claims. Moreover, regulation of filter cigarettes as devices is precluded by statutes regulating cigarettes that preempt action by federal agencies of the sort urged on FDA in

this proceeding. FDA has no authority to regulate filter cigarettes, and it should reject the Panel's recommendation.

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